

by 20% indicating reduction of LV filling pressure, the LVEF by Teicholz increased from 39% up to 45% (15%), by Simpson decreased from 45% to 40% by reducing 8.8%, cardiac output decreased from 2.61 l/min to 2.31 l/min during balloon inflation.

**Conclusions:** We are reporting the first experience in humans of a new method for intermittent preload reduction in patients with CHF. The beneficial hemodynamic and echocardiographic changes obtained in this patient suggest that this new procedure may play role in the treatment of patients with CHF. Large studies are needed to further evaluate this new procedure.

#### TCT-429

##### Fetal Pulmonary Valvuloplasty. In-Utero and Post-Natal Outcomes

Carlos Pedra<sup>1</sup>, Fabio Peralta<sup>2</sup>, Rodrigo Costa<sup>3</sup>, Marcelo Ribeiro<sup>4</sup>, Jose C. Fernandes<sup>5</sup>, Carlos R. Ferreiro<sup>5</sup>, Solange C. Gimenez<sup>5</sup>, Ieda Jatene<sup>5</sup>, Simone Pedra<sup>4</sup>

<sup>1</sup>Hospital do Coração and Instituto Dante Pazzanese, São Paulo, Brazil, <sup>2</sup>Dante Pazzanese, Sao Paulo, Brazil, <sup>3</sup>Hospital do Coração and Instituto Dante Pazzanese, sSao Paulo, Brazil, <sup>4</sup>Hospital do Coração and Instituto Dante Pazzanese, Sao Paulo, Brazil, <sup>5</sup>Hospital do Coração, Sao Paulo, Brazil

**Background:** There is a paucity of data regarding the feasibility, safety and efficacy of fetal pulmonary valvuloplasty (FPV) for pulmonary atresia or stenosis with intact interventricular septum (PA/PS/IVS) and evolving hypoplastic right heart syndrome (HRHS) diagnosed in-utero. We report in-utero and post natal outcomes of this procedure.

**Methods:** FPV was performed under maternal spinal anesthesia and fetal general anesthesia by a multi-disciplinary team under echo monitoring. A 15 cm long 17 G Chiba needle was used to access the apex of the RV. The pulmonary valve (PV) was perforated (when atretic) either with the needle or using a stiff coronary wire. Pre-mounted systems with coronary balloons (1.2-1.5 times the valve annulus) over coronary wires were advanced.

**Results:** From 01/08, 10 fetuses (6 PS/ 4 PA; mean age:  $27 \pm 2$  weeks) underwent 11 procedures. There were 2 failures. 2. One had a successful repeated procedure 2 weeks afterwards. There were no maternal complications. The valve was successfully crossed and dilated in 9 with echo evidence of forward flow and pulmonary insufficiency. Ductal spasm was observed in 4. Pericardial effusion requiring drainage was observed in all but one patient. One patient was born at elsewhere and underwent a BTT shunt and is now 3 months. Two fetuses are still in-utero. Six patients were born at our center and underwent neonatal pulmonary valvuloplasty and ductal stenting and were followed over a median post-natal period of 12 months (6-48). In these patients there was a significant and progressive increase in RV size (Z value of the TV, RV length) from the initial in-utero to the last echo assessment and all achieved an eventual BVC and spontaneous closure of the ductal stent with Sats > 90%.

**Conclusions:** FPV followed by neonatal valvuloplasty and ductal stenting was an effective means to achieve adequate RV growth and a BVC in fetuses with PA/PS/IVS and evolving HRHS. FPV is technically demanding and frequently results in pericardial effusion requiring drainage. The procedure seems to be safe to the mother. More patients are needed to draw stronger conclusions.

#### TCT-430

##### A Long Term Lumen Remodeling Analysis of a Novel Non-Drug Eluting Bioabsorbable Stent in Porcine Coronary Arteries

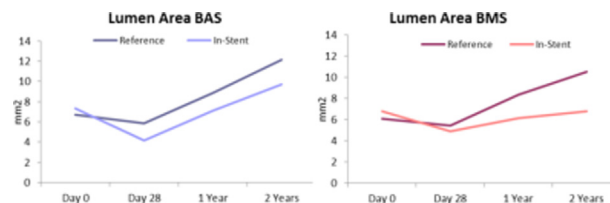
Carlos A. Gongora<sup>1</sup>, Masahiko Shibuya<sup>1</sup>, Kamal Razipoor<sup>2</sup>, Chang Lee<sup>2</sup>, Jenn McGregor<sup>1</sup>, Yanping Cheng<sup>1</sup>, Armando Tellez<sup>1</sup>, Jose V. Narvaez<sup>3</sup>, Edward A. Estrada<sup>4</sup>, Juan Granada<sup>4</sup>, Greg L. Kaluz<sup>5</sup>

<sup>1</sup>Cardiovascular Research Foundation, Orangeburg, NY, <sup>2</sup>Amaranth Medical, Inc., Mountain View, CA, <sup>3</sup>Skirball Center for Cardiovascular Research, Orangeburg, NY, <sup>4</sup>CRF, Orangeburg, United States, <sup>5</sup>Cardiovascular Research Foundation, Orangeburg, United States

**Background:** Degradation of bioabsorbable stents (BAS) has been shown to allow restoration of the treated segment's plasticity and reactivity to those resembling a non-stented artery, a desirable feature unattainable with metallic stents (BMS). We aimed to evaluate by OCT the long term dynamic changes in arterial geometry in response to a novel non-drug eluting BAS as compared to BMS.

**Methods:** Thirty-five coronary arteries of 13 swine received BAS (Amaranth Medical, Mountain View, CA n=22) or BMS (Liberte® Boston Scientific, Natick, MA n=13). Optical coherence tomography (OCT) was done at day 0, day 28 (BAS, n=22; BMS, n=13), 1 year and 2 years (BAS, n=6; BMS, n=4).

**Results:** The lumen areas of reference segments increased over time, but less for the BMS-caged segments (Day 0= $6.1 \pm 1.8$ mm<sup>2</sup>, 2 Years= $10.6 \pm 2.9$ mm<sup>2</sup>) than for the BAS-treated arteries (Day 0= $6.7 \pm 1.9$ mm<sup>2</sup>, 2 Years= $12.1 \pm 0.4$ mm<sup>2</sup>). BMS showed lumen area loss at 28 days as expected due to neointimal formation, and then minimal lumen area variance over time up to 2 years (Day 0= $6.79 \pm 1.7$ mm<sup>2</sup>, 2 Years= $6.78 \pm 2.25$ mm<sup>2</sup>). In contrast, in BAS the early lumen area loss present at 28 days inverted into lumen gain that corresponded with the scaffold mechanics paralleling the artery growth and allowing the treated segment to remodel (Day 0= $7.31 \pm 0.9$ mm<sup>2</sup>, 2 Years= $9.71 \pm 1.58$ mm<sup>2</sup>, Figure).



**Conclusions:** Restoration of the treated segment's ability to grow and remodel, with late lumen area gain as a consequence, appear to be a reproducible and inherent pattern of non-drug eluting bioabsorbable stent behavior in the porcine coronary model.

#### TCT-431

##### Long-term Angiographic and Optical Coherence Tomography Follow-up of XINSORB Scaffold in Porcine Coronary Model

Yizhe WU<sup>1</sup>, Li SHEN<sup>1</sup>, Zhifeng YAO<sup>1</sup>, Lei GE<sup>1</sup>, Qibing Wang<sup>1</sup>, Juying Qian<sup>1</sup>, Xi HU<sup>2</sup>, Jian XIE<sup>2</sup>, Junbo GE<sup>1</sup>

<sup>1</sup>Shanghai Institute of Cardiovascular Diseases, Shanghai, China, <sup>2</sup>Shanghai Weite Biotechnology Co., Ltd., Shanghai, China

**Background:** We designed the first poly-L-lactic acid XINSORB scaffold in China. Long-term morphological results of this kind of scaffold were explored in a porcine coronary model.

**Methods:** XINSORB scaffold (3.0mm in diameter and 15mm in length) were implanted into porcine coronary arteries with a reference vessel diameter ranging from 2.5 to 2.8mm, using a 1.1:1 stent-to-artery ratio. Angiogram and optical coherence tomography (OCT) test were performed after implantation and at 1, 3, 12, and 18-month follow-up.

**Results:** Total 28 mini pigs were enrolled and 56 scaffolds were deployed. At 1, 3, 12, and 18-month, 8, 8, 10, and 10 scaffolds were examined respectively. Angiogram after procedure showed that proximal, in-scaffold, and distal minimal luminal diameter were  $2.93 \pm 0.28$ mm,  $2.78 \pm 0.26$ mm and  $2.73 \pm 0.30$ mm. The corresponding percentage of diameter stenosis (%DS) was  $5.7 \pm 4.0\%$ ,  $7.0 \pm 4.1\%$  and  $6.7 \pm 4.1\%$  respectively. At 1-month follow-up, proximal, in-scaffold, and distal late luminal loss (LLL) of scaffold were  $0.53 \pm 0.41$ mm,  $0.68 \pm 0.42$ mm and  $0.65 \pm 0.24$ mm, while %DS were  $9.5 \pm 7.7\%$ ,  $17.6 \pm 16.8\%$  and  $10.5 \pm 7.4\%$ . At 3-month, proximal, in-scaffold, and distal LLL were  $0.23 \pm 0.48$ mm,  $0.77 \pm 0.48$ mm and  $0.11 \pm 0.35$ mm, while %DS were  $14.5 \pm 9.4\%$ ,  $31.9 \pm 13.6\%$  and  $5.4 \pm 3.6\%$ . At 12-month, proximal, in-scaffold, and distal LLL were  $-0.13 \pm 0.45$ mm,  $0.28 \pm 0.41$ mm and  $0.18 \pm 0.48$ mm, while %DS were  $2.4 \pm 2.9\%$ ,  $14.1 \pm 9.1\%$  and  $8.6 \pm 8.7\%$ . At 18-month, proximal, in-scaffold, and distal LLL were  $0.37 \pm 0.57$ mm,  $0.09 \pm 0.31$ mm and  $-0.01 \pm 0.41$ mm, while %DS were  $3.9 \pm 4.6\%$ ,  $13.7 \pm 7.3\%$  and  $6.9 \pm 5.2\%$ . OCT demonstrated that luminal area, scaffold area, neointimal area and percentage of area stenosis were  $5.95 \pm 1.63$ mm<sup>2</sup>,  $8.08 \pm 1.16$ mm<sup>2</sup>,  $2.12 \pm 0.67$ mm<sup>2</sup> and  $25.8 \pm 10.6\%$  at 1 month,  $4.02 \pm 0.96$ mm<sup>2</sup>,  $7.91 \pm 0.53$ mm<sup>2</sup>,  $2.89 \pm 0.45$ mm<sup>2</sup> and  $37.9 \pm 9.7\%$  at 3 month,  $5.96 \pm 0.82$ mm<sup>2</sup>,  $8.09 \pm 0.74$ mm<sup>2</sup>, and  $2.07 \pm 0.36$ mm<sup>2</sup> and  $24.1 \pm 7.3\%$  at 12 month and  $6.84 \pm 0.77$ mm<sup>2</sup>,  $8.74 \pm 0.82$ mm<sup>2</sup>,  $1.94 \pm 0.56$ mm<sup>2</sup> and  $19.7 \pm 6.9\%$  at 18 month. Preserved box of scaffold was 100%, 97.6%, 92.1% and 89.4% at each time point.

**Conclusions:** Neointimal hyperplasia of XINSORB scaffold was prominent at 3-month. After that, LLL and %DS were noticeably reduced. LA at 18-month was significantly larger than that at 3-month with a constant scaffold area.

#### TCT-432

##### Acute Left Ventricular Unloading and Delayed Coronary Reperfusion Promotes Stromal Cell Derived Factor-1 (SDF-1) Expression and Cardioprotective Signaling in Acute Myocardial Infarction

Navin K. Kapur<sup>1</sup>, Vikram Paruchuri<sup>2</sup>, Xiaoying Qiao<sup>2</sup>, Kevin Morine<sup>2</sup>, Wajih Syed<sup>2</sup>, Sam Dow<sup>2</sup>, Nimish Shah<sup>2</sup>, Natesa Pandian<sup>1</sup>, Richard H. Karas<sup>2</sup>

<sup>1</sup>Tufts University, Boston, Massachusetts, <sup>2</sup>Tufts Medical Center, Boston, MA

**Background:** Ischemia-reperfusion injury (IRI) remains a major determinant of mortality in acute myocardial infarction (AMI). Stromal cell-derived factor-1 (SDF-1) is a chemokine that promotes myocardial salvage by activating cardioprotective signaling via Akt, ERK, and STAT-3. No studies have targeted initially reducing left ventricular stroke work (LVSW) to limit IRI in AMI. The Impella CP axial-flow pump reduces LVSW. We tested the hypothesis that first reducing myocardial work and delaying coronary reperfusion reduces infarct size by activating cardioprotective signaling pathways.

**Methods:** AMI was induced by occlusion of the left anterior descending artery (LAD) via angioplasty for 90 minutes in 50kg male Yorkshire swine (n=5/group). In Group 1, the LAD was reperused for 120 minutes. In Group 2, after 90 minutes of ischemia the Impella CP device was activated and the LAD left occluded for an additional 60 minutes (150 minutes of LAD occlusion total), followed by 120 minutes of reperfusion. The Impella CP was active throughout reperfusion. Western blot analysis quantified myocardial kinase activity.